IAP13 Rec'd PCT/PTO 0.8 JAN 2007

MANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE CUSTOMER NO. 22,852 (DO/EO/US) ATTORNEY'S DOCKET NUMBER: 10084-0004.00000 **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** U.S. APPLICATION NO. if known, see 37 CFR 1.5(10/571,511 NATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED September 9, 2004 September 11, 2003 TITLE OF INVENTION METHOD AND KIT FOR DETECTING PROLIFERATIVE DISEASES CAUSING SCLEROSIS, PREVENTIVE AND/OR REMEDY FOR PROLING RATIVE DISEASES CAUSING SCLEROSIS AND METHOD AND KIT FOR IDENTIFYING SUBSTANCE EFFICACIOUS IN PREVENTING AND/OR TREATING PROLIFERATIVE DISEASES CAUSING SCLEROSIS APPLICANT(S) FOR DO/EO/US Toshio DOI et al. Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C 371. Ø This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 3. (5), (6), (9) and (21) indicated below. Ø The US has been elected (Article 31) A copy of the International Application as filed (35 U.S.C. 371 (c)(2)). 5. is attached hereto (required only if not communicated by the International Bureau). a. × has been communicated by the International Bureau. b. is not required, as the application was filed with the United States Receiving Office (RO/US). C. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. a. has been previously submitted under 35 U.S.C. 154(d)(4). h. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. d. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). \boxtimes 'An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 9. An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371 (c)(5)). Items 11 to 20 below concern document(s) or information included: Information Disclosure Statement under 37 CFR 1.97 and 1.98 11. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. 14. 15 A Substitute specification. 16 A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 18. 📮 A second copy of the published International Application under 35 U.S.C. 154 (d)(4). 19. A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4). CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL" I hereby certify that this correspondence is 20. Other items or information: being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated below and is addressed to the Mail Stop Commissioner for Patents, P.O. Box 1450. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Date: January 8, 2007 Express Mail Label # EV 955 595 122 US By: Elizabeth Nesbitt \boxtimes copy of Notification of Missing Requirements

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/571,511			INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER 10084-0004.00000			
	The following food bo	- basa submittadi	PCT/JP2004/013124					
21. 🛛	The following fees har BASIC NATIONAL FE			\$300.00		CALCULATIONS	PTO Use Only	
						\$ 00.00		
22.						\$ 00.00		
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)						\$ 00.00	-	
		TOTAL of 2	1, 22 and 23 =			\$ 00.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.								
Total Sheets		Extra Sheets	Number of each additional 50 or fraction Rate thereof (round up to a whole number)			-		
1	03 - 100 =	3 /50=	. 1		x \$250.00	\$250.00		
	Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).							
CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE				
Total Claims		17 - 20		x \$50.00		\$		
Independen		17 -3	= 14	x \$200.0		\$ 00.00 \$		
MULTIPLE	MULTIPLE DEPENDENT CLAIM(S) (if applicable) +\$360.00							
TOTAL OF ABOVE CALCULATIONS =								
☐ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.								
	SUBTOTAL =							
	Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest priority date (37 CFR 1.492(i)). +							
TOTAL NATIONAL FEE =								
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.								
/2007 MKAYPAGH 00000033 060916 10571511 TOTAL FEES ENCLOSED =								
:1681 :1617	130.00 DA	-	•			Amount to be refunded:	\$	
a. 🗆 A	check in the amount o	f \$	to cover the above	face is anclosed		charged:	\$	
a. ☐ A check in the amount of \$ to cover the above fees is enclosed. b. ☑ Please charge my Deposit Account No. <u>06-0916</u> in the amount of \$ <u>\$420.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.								
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0916. A duplicate copy of this sheet is enclosed.								
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.								
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.								
SEND ALL CORRESPONDENCE TO:								
901 New Yo	enderson, Farabow, G rk Avenue, N.W. , DC 20001-4413	Sarrett & Dunner, L.L.P.	SIGNAT	Chris T. Mizumoto				
DATED: Jar	uary 8, 2007			NAME/REGISTRA	TION NUMBER	₹		



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United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE UNITED STATES DEPARTMENT OF COMMI United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Viginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO. 10084-0004.00000

10/571,511

Toshio Doi

INTERNATIONAL APPLICATION NO.

PCT/JP04/13124

I.A. FILING DATE PRIORITY DATE

09/09/2004

09/11/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER

901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413

NOV 1 0 2006

CONFIRMATION NO. 8941 371 FORMALITIES LETTER

OC000000021164967

Date Mailed: 11/08/2006

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/10/2006
- Copy of the International Search Report filed on 03/10/2006
- Preliminary Amendments filed on 03/10/2006
- Information Disclosure Statements filed on 03/10/2006
- Biochemical Sequence Diskette filed on 03/10/2006
- Biochemical Sequence Listing filed on 03/10/2006
- U.S. Basic National Fees filed on 03/10/2006
- Priority Documents filed on 03/10/2006
- Specification filed on 03/10/2006
- Claims filed on 03/10/2006
- Abstracts filed on 03/10/2006
- Drawings filed on 03/10/2006
- Paper nucleotide sequence listings filed on 03/10/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$380 for a Large Entity:

- \$130 Surcharge.
 - A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of
 the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as
 indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a
 substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content
 of the sequence listing information recorded in computer readable form is identical to the written (on paper
 or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR
 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).
 - The specification and drawings contain more than 100 pages. Applicant owes \$250 for 3 pages in excess
 of 100 pages for a non-small entity.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FREDERICK SMITH

Telephone: (703) 308-9140 EXT 210

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/681 514	D.CT!/TD0.1/10.10.1	10001 0001 00000

FORM PCT/DO/EO/905 (371 Formalities Notice)